DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0229]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Continuous Marketing Applications: Pilot 2–Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Continuous Marketing Applications: Pilot 2–Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act (OMB Control Number 0910–0518—Extension)

FDA is requesting OMB approval under the PRA (44 U.S.C. 3507) for the reporting and recordkeeping requirements contained in the guidance for industry entitled ''Continuous Marketing Applications: Pilot 2–Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA.'' This guidance discusses how the agency will implement a pilot program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of the development of certain Fast Track drug and biological products. Applicants are being asked to apply to participate in the Pilot 2 program.

In conjunction with the June 2002 reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA), FDA agreed to meet specific performance goals (PDUFA Goals). The PDUFA Goals include two pilot programs to explore the continuous marketing application (CMA) concept. The CMA concept builds on the current practice of interaction between FDA and applicants during drug development and application review and proposes opportunities for improvement. Under the CMA pilot program, Pilot 2, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet

medical need) are eligible to participate in the program. Pilot 2 is an exploratory program that will allow FDA to evaluate the impact of frequent scientific feedback and interactions with applicants during the investigational new drug application (IND) phase. Under the pilot program, a maximum of one Fast Track product per review division in CDER and CBER will be selected to participate. This guidance provides information regarding the selection of participant applications for Pilot 2, the formation of agreements between FDA and applicants on the IND communication process, and other procedural aspects of Pilot 2. FDA began accepting applications for participation in Pilot 2 on October 1, 2003.

The guidance describes one collection of information: Applicants who would like to participate in Pilot 2 must submit an application (Pilot 2 application) containing certain information outlined in the guidance. The purpose of the Pilot 2 application is for the applicants to describe how their designated Fast Track product would benefit from enhanced communications between FDA and the applicant during the product development process.

FDA's regulation at § 312.23 (21 CFR 312.23) states that information provided to the agency as part of an IND must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs. Both 21 CFR part 312 and FDA Form 1571 have a valid OMB control number (OMB control number 0910–0014), which expires January 31, 2006.

In the guidance document, FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) ask that a Pilot 2 application be submitted as an amendment to the application for the underlying product under the requirements of § 312.23; therefore, Pilot 2

applications should be submitted to the agency in triplicate with Form FDA 1571. The agency recommends that a Pilot 2 application be submitted in this manner for two reasons: (1) To ensure that each Pilot 2 application is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the Pilot 2 application is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the agency to monitor progress on activities.

Under the guidance, the agency asks applicants to include the following information in the Pilot 2 application:

- Cover letter prominently labeled ''Pilot 2 application;''
- IND number;
- Date of Fast Track designation;
- Date of the end-of-phase 1 meeting, or equivalent meeting, and summary of the outcome;
- A timeline of milestones from the drug or biological product development program, including projected date of new drug application (NDA)/ biologic licensing application (BLA) submissions;
- Overview of the proposed product development program for a specified disease and indication(s), providing information about each of the review disciplines (e.g., chemistry/ manufacturing/ controls, pharmacology/ toxicology, clinical, clinical pharmacology and biopharmaceutics);
- Rationale for interest in participating in Pilot 2, specifying the ways in which development of the subject drug or biological product would be improved by frequent scientific feedback and interactions with FDA and the potential for such communication to benefit public health by improving the efficiency of the product development program; and
- Draft agreement for proposed feedback and interactions with FDA.

This information will be used by the agency to determine which Fast Track products are eligible for participation in Pilot 2. Participation in this pilot program will be voluntary.

Based on the number of approvals for Fast Track designations and data collected from the review divisions and offices within CDER and CBER, FDA estimates that in fiscal year 2002, 109 drug product applications and 46 biological products had Fast Track designation. FDA anticipates that approximately 85 drug product applicants (respondents) and approximately 29 biological product applicants (respondents) will submit at least one Pilot 2 application. Based on information collected from offices within CDER and CBER, the agency further anticipates that the total responses, i.e., the total number of applications received for Pilot 2, will be 90 for drug products and 35 for biological products. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitting in a Pilot 2 application in accordance with the guidance, is estimated to be approximately 80 hours. Based on FDA's experience, we expect it will take respondents this amount of time to obtain and draft the information to be submitted with a Pilot 2 application. Therefore, the agency estimates that applicants will use approximately 10,000 hours to complete the Pilot 2 applications.

On September 29, 2003, this guidance was approved on an emergency basis, which expires on March 30, 2004. This notice of request is to receive approval in the normal PRA process.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Pilot 2 Application	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
CDER	85	1.06	90	80	7,200
CBER	29	1.20	35	80	2,800
Total					10,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of November 20, 2003, (68 FR 65457), FDA announced the availability of the guidance and requested comments for 60 days on the information collection. One comment was received that did not pertain to the information collection.

Dated: February 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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